

QUALITY ASSURANCE AID FOR CERTIFICATE OF WAIVER LABORATORIES

CLIA regulations require facilities with a Certificate of Waiver (CoW) to:

Perform only CLIA waived tests (this information may be printed on the box, printed in the package insert, in a letter to the manufacturer from Health and Human Services, or found on the web at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm and / or www.cms.gov/clia).

Follow the manufacturer's instructions completely. An instruction booklet or sheet is found in every waived kit package or waived test reagent container. Make sure you have the most current package insert on hand for every waived test you do in your facility.

Who can direct a CoW? CLIA has no personnel requirements for CoW facilities. The director is responsible to make certain the two requirements listed above are followed and that the facility's certificate is current.

Who can perform waived tests? CLIA has no personnel requirements for CoW facilities. Anyone who is properly trained and remains competent can perform waived tests.

Notification: CoW facilities must notify CLIA's state agency, in writing, before changing to or adding a non-waived test. Center for Medicare and Medicaid Services (CMS) also requires a CoW facility to notify the state agency, in writing, of any change in director, location, ownership or complete testing termination.

No certificate. If you can't find your certificate or it has expired and you don't have a current one, contact your state agency. You are billed a recertification fee every two years – at least 6 months in advance. Your certificate is mailed the first of the month in which it expires.

Do not use your waived kits or reagents after they expire. The manufacturer will not guarantee the results and your patients may suffer from inaccurate test results.

If a salesperson drops off a kit or test reagent for you to try, make certain it is waived. Most companies make waived and non-waived kits for the same test.

When you receive an order, make certain it is the brand you want and that it will not outdate before you can use it up. Companies should take back a product with a short outdate and give you one you can use.

Most CLIA waived tests have a special CPT code for billing Medicare and Medicaid. The codes may change annually. Medicare publishes updates in their monthly Part B Newsletters. Contact your provider for information on which codes to use or check the CMS website listed above.

You can bill only for testing you perform in your facility. Tests you collect or process and cultures you put onto media to send to a reference lab are not CLIA tests in your facility. The reference lab must bill for them. Make certain your reference lab has a current CLIA certificate.